

REMARKS/ARGUMENTS

Claims 5, 8-16 and 18 are currently pending. Applicants have amended claims 5 and 18. Applicants respectfully submit that the claims are allowable in view of the amendments and the following arguments.

Applicants first submit that the claims have been amended. Specifically, claims 5 and 18 have been amended to clarify that (1) the contacting step is the first step, and it is a capture step (US published application §0038, 1st line), and (2) host cell residues are removed in the first step (§0038, latter part). Capture step is further defined as the initial step of a separation procedure (§0032). Applicants submit that the amendments are fairly based on the specification and do not add any new matter.

Claims 5, 8-10, 16 and 18 stand rejected as either being anticipated under 35 U.S.C. §102(b) or 102(e) by Belew et al. (US 6,852,230 or WO 02/053288), or in the alternative, rendered obvious by Belew et al. Applicants respectfully disagree.

Applicants first submit that the claims have been amended. The claims now clearly specify that the contacting step is a first step which is a capture step. The claims further clarify that the process starts from a cell culture liquid or a fermentation broth, and the capture step removes the host cell residues. Applicants submit that the claimed process using the particular resin gave surprisingly good clearance of impurities in fermentation broths. For example, see the removal of host cell proteins shown in Example 3 and the corresponding before/after chromatograms in Figures 2

and 3. It is clear that “the contaminating proteins were reduced to a great extent” (see §0092 - the last paragraph in Example 3).

In response to Applicants’ earlier arguments, the Examiner states that Belew et al. teaches use of their multi-modal chromatography (MMC) resins on fermentation broths etc (col. 13, lines 42-45) and the Examiner questions why the skilled person would consider the Belew et al. resins unusable with fermentation broths and cell culture liquids.

Applicants submit that Belew et al. do not give any indication that the resins should be effective in removing host cell residues. The only selectivity demonstrated in Belew et al. is between protein and salt, while the claimed invention clearly demonstrates a remarkable selectivity between IgG and host cell proteins (Figure 2, SEC chromatogram of feed vs. Figure 3, SEC chromatogram after MMC resin). Thus the most evident difference from Belew et al. is that the claimed invention achieves protein-protein selectivity, which is not taught or suggested in Belew et al. Further, the Belew et al. col. 13, lines 42+ discussion cited by the Examiner concerns removal of a substance from the liquid (heading line 17), which in the Belew et al. context means that this is the target substance that binds to column while the salts are washed off. Applicants submit that this discussion is only used in a desalting context. In col. 1, lines 10-20 Belew et al. defines a desalting procedure where the substance is bound to the ion exchanger in question and then desorbed. Applicants submit that conventional cation exchangers give protein-protein selectivity at low salt

concentrations. It is therefore not obvious that multi-modal cation exchangers should give good protein-protein selectivity at high salt concentration.

The rejections of claims 5, 8-10, 16 and 18 as either being anticipated or rendered obvious by Belew et al. should be withdrawn.

Claims 5 and 11-15 stand rejected as being obvious over Belew et al. in view of Prior et al. (US 5,118,796). Applicants respectfully disagree.

Belew et al. has been discussed above.

As stated above, the claimed invention provides good selectivity between IgG and host cell proteins within a feed. The claims clearly state that the feed was not subjected to dilution or desalting by diafiltration or dialysis as is taught in Prior et al. (where conventional cation exchangers are used). Applicants submit that the additional dilution/desalting operation of Prior et al. is precisely what is avoided by the present technology.

Applicants submit the claims rejections under 35 U.S.C. §103(a) over Belew et al. in view of Prior et al. should be withdrawn.

Applicants respectfully assert that the claims are in allowable form and earnestly solicit the allowance of the claims 5, 8-16 and 18.

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Early and favorable consideration is respectfully requested.

Respectfully submitted,

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